REMARKS

This Amendment is being filed in response to the Final Office Action mailed from the U.S. Patent and Trademark Office (USPTO) on March 5, 2004, in which claims 1-31 were rejected. With this Amendment, claims 1, 9, 11, 12, 17, 22-24, 26 and 28-30 are amended. As such, Applicants respectfully request reconsideration and allowance of pending claims 1-31.

Applicants hereby gratefully acknowledge the telephone conference with Examiner Bradford C. Pantuck on April 27, 2004, wherein Applicants' attorney David J. Dykeman and Examiner Pantuck discussed the Final Office Action, the cited prior art and Applicants' proposed amendments.

The Office Action rejected claims 1-21 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,692,139 to Stiles ("the Stiles '139 patent"). The Office Action rejected claim 17 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,494,893 to Dubrul et al. ("the Dubrul et al. '893 patent") in view of U.S. Patent No. 5,971,983 to Lesh ("the Lesh '983 patent"). The Office Action also rejected claims 17-30 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,709,359 to Bufalini ("the Bufalini '359 patent") in view of the Lesh '983 patent.

Anticipation Rejections Under 35 U.S.C. 102(b)

The Final Office Action rejected claims 1-21 under 35 U.S.C. 102(b) as being anticipated by the Stiles '139 patent. The Office Action states on pages 4-6 that Stiles discloses a vascular introducer for insertion into a blood vessel:

> Regarding Claims 1, 2, and 9-12 Stiles discloses a vascular introducer for insertion into a blood vessel. His introducer has an elongated shaft (1) and an anchoring mechanism (5). The anchoring mechanism (5) has a retracted position [see Fig. 1] and an extended position [see Fig. 3] in which the anchor is able to engage the inner surface of the artery [Column 3, lines 54-57].

To anticipate a claim, the reference must teach every element of the claim. M.P.E.P. 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987);

M.P.E.P. 2131. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989); M.P.E.P. 2131.

With this Amendment, Applicants have amended independent claims 1, 9, 17 and 26 to claim a vascular introducer comprising an **anchoring mechanism comprising a plurality of wing-like anchors** wherein the **plurality of wing-like anchors engage an inner surface at a puncture site of the vascular access device** when the anchoring mechanism is in an extended position. Dependent claims 11, 12, 22-24 and 28-30 are also amended to recite a plurality of wing-like anchors. No new matter is added with this Amendment. Support for these amendments to the claims is found throughout Applicants' specification, and specifically on page 14, lines 13 through 16 as follows:

> As best shown in FIG. 1 and FIG. 4, a preferred embodiment of the present invention features the anchoring mechanism 70 including **the anchor 72 that is a wing-like object that flexes outward** from the proximal insertion end 44 of the elongated shaft 40 of the vascular introducer 10 after the vascular introducer is placed in the vascular access device 20. (Applicants' Specification; page 14, lines 13 to 16) (Emphasis Added).

None of the cited prior art patents disclose or suggest a vascular introducer comprising an **anchoring mechanism comprising a plurality of wing-like anchors** wherein the **plurality of wing-like anchors engage an inner surface at a puncture site of the vascular access device** when the anchoring mechanism is in an extended position.

Argument Regarding Stiles '139 Patent

The Stiles '139 patent discloses a device comprising a catheter for "insertion into a biological duct via a single incision remote from the vicinity of the obstruction and moved into position within the duct" (Stiles '139 patent; Col. 2, Lines 31-33). The Stiles device comprises a delivery sleeve having an aspiration tube with a rubber shield on a remote end of the aspiration tube. The Stiles delivery sleeve is inserted into the biological duct and fed through the artery to a position within the biological duct in close proximity to the obstruction. The Stiles rubber shield is deployed remote from the single incision at the site of the obstruction and serves to direct the

movement of the fragments of the obstruction within the aspiration tube. The Stiles device is shown in FIGS. 1 and 3 and is described as follows:

> According to the present invention, a device is provided for integrating the functions of aspiration, irrigation and ultrasound application within a single catheter, for insertion into a biological duct via a single incision **remote from the vicinity of the obstruction** and moved into position within the duct. (Stiles '139 patent; Col. 2, Lines 28-33) (Emphasis Added).
>
> In order to emulsify and fragment an obstruction such as a blood clot blocking the coronary artery or other artery chambers of the heart, the delivery sleeve 1 is preferably inserted into an appropriate leg artery according to well known surgical techniques, and is **fed through the artery to a position within the coronary artery or artery chamber in close proximity to the obstruction**. (Stiles '139 patent; Col. 4, Lines 18-25) (Emphasis Added).
>
> Mounted on a **remote end of aspiration tube 3** is a **folded soft springy rubber shield 5**. (Stiles '139 patent; Col. 3, Lines 38-39) (Emphasis Added).
>
> The shield 5 opens and closes between the deployed and retracted positions with an **action similar to that of opening and closing an umbrella**. (Stiles '139 patent; Col. 3, Lines 54-57) (Emphasis Added).
>
> A catheter as defined in claim 1, further including a collapsible shield connected to said first end of the aspiration tube, said shield being movable between a collapsed position within said delivery tube and a deployed position externally of said delivery tube in response to said aspiration tube being moved between said retracted and extended positions respectively, whereby **in said deployed position the shield directs removal of said fragmented matter from said vicinity** into the aspiration tube. (Stiles '139 patent; Col. 6, Lines 14-23) (Emphasis Added).

The Stiles shield does not serve as an anchoring mechanism comprising a plurality of wing-like anchors. The Stiles shield "is a folded soft springy rubber shield" and does not comprise a wing-like anchor engaging an inner surface at a puncture site of the vascular access device to secure the vascular introducer. The Stiles shield does not engage an inner surface at a puncture site of the vascular access device to secure the vascular introducer. The Stiles '139 patent discloses a device that is inserted into a "biological duct via a single incision remote from the vicinity of the obstruction" (Stiles '139 patent; Col. 2, Lines 31-32). The Stiles shield is deployed remote from the single incision at the site of the obstruction and does not engage the inner surface **at the puncture site** of the biological duct. The Stiles '139 patent offers no disclosure, teaching or suggestion for using the Stiles shield at the puncture site. Therefore,

Stiles does not disclose a vascular introducer comprising an anchoring mechanism **comprising a plurality of wing-like anchors** wherein the **plurality of wing-like anchors engage an inner surface at a puncture site of the vascular access device** when the anchoring mechanism is in an extended position. Thus, the Stiles '139 patent does not anticipate or suggest the Applicants' claimed invention and the anticipation rejection is overcome. Applicants respectfully request reconsideration and allowance of pending claims 1-31.

Obviousness Rejections Under 35 U.S.C. 103(a)

The Office Action rejected claim 17 under 35 U.S.C. 103(a) as being unpatentable over the Dubrul et al. '893 patent in view of the Lesh '983 patent. The Office Action also rejected claims 17-30 under 35 U.S.C. 103(a) as being unpatentable over the Bufalini '359 patent in view of the Lesh '983 patent.

"Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." M.P.E.P. 2143.01. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab,* 217 F.3d 1365, 1370, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000). See also *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); M.P.E.P. 2143.01.

The Office Action rejected claim 17 under 35 U.S.C. 103(a) as being unpatentable over the Dubrul et al. '893 patent in view of the Lesh '983 patent. The Office Action states on page 5 and page 6:

> Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,494,893 to Dubrul et al. in view of U.S. Patent No. 5,971,983 to Lesh. Dubrul discloses a vascular introducer (20) with an anchoring mechanism (72) into a vascular access device. The vascular introducer is hollow to accommodate various needles and other surgical devices [Column 8 line 53 - Column 9 line 10]. Dubrul discloses engaging an anchoring mechanism (72) [Column 7, lines 36-45; Column 8, lines 1-13] to the inner surface of the vascular access device at a puncture site [Column 9, lines 8-14; see Fig. 17].

> Dubrul does not disclose inserting an ultrasonic probe through his trocar. However, Lesh discloses a trocar and anchoring assembly and teaches inserting an ultrasonic probe through his assembly and into a vascular access device (such as the heart or other body organs). He does so in order to ablate debris [Column 9, lines 55-6 1]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use an ultrasonic probe in conjunction with a trocar (vascular introducer) in order to ablate tissue, as taught by Lesh.

The Dubrul et al. '893 patent discloses an apparatus and a method for forming and enlarging percutaneous penetrations comprising an elongate dilation member which receives an elongate expansion member in an axial lumen. The Dubrul et al. elongated dilation member further comprises an anchor at its distal end to be deployed after penetration but prior to expansion of the expansion member. The anchor holds the dilation member in place and prevent separation of the skin and fascial layers as the expansion member is introduced through the dilation member. The Dubrul et al. device is shown in FIGS. 1 and 4-7 and is described as follows:

> The **elongate dilation member may further comprise an anchor at its distal end to be deployed after penetration but prior to expansion.** The anchor would serve to hold the dilation member in place and to prevent separation of the skin and fascial layers as the expansion member is introduced through the dilation member. Usually, however, the inherent anchoring capacity of the tubular braid is sufficient by itself to hold the dilation member in place and prevent tissue separation, so that the anchor will not be necessary. (Dubrul et al. '893 patent; Col. 7, Lines 36-45) (emphasis added)

As shown above, Dubrul et al. does not disclose, teach or suggest extending **a plurality of wing-like anchors** from a retracted position **to beyond a proximal insertion end of an elongated shaft** of the vascular introducer. The Lesh '983 patent does not cure or offer a suggestion on how to overcome the deficiencies of the Dubrul et al. '893 patent. Thus, the obviousness rejection to claim 17 is overcome, and Applicants respectfully request reconsideration and allowance of pending claims 1-31.

The Office Action also rejected claims 17-30 under 35 U.S.C. 103(a) as being unpatentable over the Bufalini '359 patent in view of the Lesh '983 patent. The Bufalini '359 patent discloses an expanded trocar assembly with an expandable distal end. More specifically,

the Bufalini '359 device comprises a distal end slit into four or five ribs that expand into a funnel shape when they are not restrained (Bufalini '359 patent; Col. 3, Lines 56-60). The Bufalini '359 patent does not disclose a vascular introducer comprising an anchoring mechanism comprising a plurality of wing-like anchors wherein the plurality of wing-like anchors engage an inner surface at a puncture site of the vascular access device when the anchoring mechanism is in an extended position. The Lesh '983 patent does not cure or offer a suggestion on how to overcome the deficiencies of the Bufalini '359 patent. Thus, the obviousness rejection to claims 17-30 is overcome, and Applicants respectfully request reconsideration and allowance of pending claims 1-31.

With this Amendment, Applicants have amended claims 1, 9, 11, 12, 17, 22-24, 26 and 28-30 to claim a vascular introducer comprising an anchoring mechanism comprising a plurality of wing-like anchors wherein the plurality of wing-like anchors engage an inner surface at a puncture site of the vascular access device when the anchoring mechanism is in an extended position. As such, Applicants respectfully request reconsideration and allowance of pending claims 1-31.

With this Amendment, Applicants have made an earnest effort to respond to all issues raised in the Office Action of March 5, 2004, and to place all claims presented in condition for allowance. No Amendment made was for the purpose of narrowing the scope of any claim, unless Applicants have argued herein that such amendment was made to distinguish over a particular reference or combination of references.

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

Respectfully submitted,

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